

REMARKS

The present invention relates in part to assay devices comprising elements for the controlled flow, delivery, incubation, separation, washing and other steps of the assay process. The devices of the present invention can provide advantageous capture efficiencies and sensitivities for the assay of a plurality of target molecules.

Claims 74-84 and 92-100 are presently pending, with claims 81 and 99 amended herein in accordance with the Examiner's suggestion on page 2 of the Office Action.

Applicant expressly reserves the right to pursue subject matter no longer or not yet claimed in the instant application in one or more applications that may claim priority hereto.

Applicant respectfully requests reconsideration of the claimed invention in view of the following remarks and terminal disclaimers provided herewith.

Art Based Remarks

1. Obviousness-Type Double Patenting

Applicant respectfully traverses the rejection of claims 74-84 and 92-100 on the ground of obviousness-type double patenting over claims 1-15 of U.S. Patent No. 5,458,852.

The patent law requires that the Examiner provide reasoning for why a rejection is appropriate. In the case of obviousness-type double patenting, MPEP § 804(II)(B)(1) sets forth the analysis to be employed when making the appropriate analysis. In the present case, the Examiner states that the claims of U.S. Patent No. 5,458,852 refers to a device having "at least one zone to bind an analyte and hydrophilic/hydrophobic regions to direct the fluid." Office Action, page 4.

It is respectfully submitted that this rationale is insufficient to support a *prima facie* rejection and is so limited in detail as to render it impossible for Applicant to properly rebut the

rejection. For example, the assertion that the patented claims describe “at least one zone to bind an analyte” is incorrect. Nevertheless, Applicant points out that the pending claims differ from the patented claims in that the former includes “a plurality of discrete capture zones” and “receptors immobilized to said surface.” It is apparent that these features constitute a patentable species of the “diagnostic element” of the patented claims. Reconsideration and withdrawal of the rejection is respectfully requested.

2. 35 U.S.C. § 102

Applicant respectfully traverses the rejection of claims 74-81 and 92-99 under 35 U.S.C. §102(b), as allegedly being anticipated by Stöcker, U.S. Patent 4,647,543 (hereinafter “Stöcker”).

In order to anticipate a claim, a single prior art reference must provide each and every element set forth in the claim. Furthermore, the claims must be interpreted in light of the teaching of the specification. *In re Bond*, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). *See also* MPEP §2131.

In rejecting the claims, the Examiner points with particularity to element 1(a) of Figure 6a in Stöcker as allegedly disclosing the claimed invention. Specifically, in the paragraph bridging pages 2 and 3 of the Office Action, the Examiner cites the following portions of Stöcker regarding the various claim elements:

Claim 74	Stöcker reference cited by Examiner
An assay device for detecting a plurality of target ligands in a sample	Fig. 6(a)
a nonporous smooth surface or a nonporous textured surface, said nonporous textured surface comprising one or more depressions or protrusions extending between 1 nm and 0.5 mm from said nonporous textured surface	Plate (2), and “column 5, lines 59+ and claim 8 teach the surface is not flat and has ‘depressions’ where the sample can be trapped. This has been read on the claimed ‘textured surface’”

a plurality of discrete capture zones on said surface	Supports 1(a)
each said capture zone comprising receptor immobilized to said surface or immobilized on particles immobilized to said surface, wherein said receptors are capable of binding one or more of said plurality of target ligands,	“Support 1(a) has been read on the claimed particles that immobilize the sample”
wherein said particle size range is from 1 nm to 5 μ m,	Nothing in Stocker is cited as providing particles meeting this size limitation
wherein said capture zones occupy one or more discrete hydrophilic regions of said surface delimited by an adjacent hydrophobic region of said surface.	Supports 1(a) are “within a hydrophilic area (3) for sample capture and a surrounding hydrophobic area (4)”

Applicant respectfully submits that the Examiner’s recitation of features from Stöcker does not properly address the claimed elements and thus fails to establish a *prima facie* case of anticipation. For example, the statement that support 1(a) of Stöcker has been read on the claimed particles that immobilize the sample” is irrelevant because the claims do not specify “particles that immobilize the sample.” Rather, in certain claimed embodiments, particles comprising receptors that bind one or more of a plurality of target ligands are immobilized to discrete zones on a non-porous surface. *See, e.g.*, claim 74. The rejection is therefore deficient because it is based on an improper understanding of the claims.

In addition, in the last action, the Examiner has offered a new claim interpretation of the claims which Applicant respectfully submits would not be adopted by one of ordinary skill. The relevant language is quoted from paragraphs bridging pages 4-5 of the Office Action.

The Office notes the instant claim language only specifies the particle size in the alternative (e.g. or immobilized on particles immobilized to said surface, wherein the particle size range is from 1 nm to 5 nm . . . “). The Office has read claims as only requiring

“each said capture zone comprising receptors immobilized to said surface” which does not carry particle size limitations.

Although claims are examined under their broadest reasonable interpretation, that interpretation must be both reasonable and consistent with the interpretation one of skill in the art would reach. To reiterate, the claims specify two options for receptor immobilization: (i) “receptor immobilized to said surface” comprising the plurality of discrete capture zones; and (ii) receptor “immobilized on particles immobilized to said surface” comprising the plurality of discrete capture zones.

Applicant respectfully submits that the plain language of the claims makes it abundantly clear that “receptor immobilized to said surface” refers to receptor that is linked to the non-porous smooth or non-porous textured surface that comprises a plurality of discrete capture zones; and that this is distinct from the second option where receptor is linked to a separate solid phase, in this case a particle of the appropriate dimension, where the separate particle is immobilized to the non-porous smooth or non-porous textured surface that comprises a plurality of discrete capture zones. In the first instance, receptor may be immobilized to said surface by any of a variety of chemistries known in the art, with linking both direct and indirect. Nevertheless, this clearly differs from the latter instance where receptor is immobilized to a separate solid phase such as a particle, again by any of a variety of chemistries known in the art. One of ordinary skill would not adopt the Examiner’s interpretation that attaching to a separate solid phase such as a particle is the same as attaching to the device surface because to do so effectively renders the reference to particles and the particle size limitation meaningless.

The most relevant item in Stöcker figure 6(a) that corresponds to the non-porous smooth or non-porous textured surface would plate 2. Immobilizing to glass fragments that comprise support 1(a) of Stöcker is different from immobilizing to the surface of plate 2. As such, Stöcker does not disclose a non-porous smooth or non-porous textured surface that has a plurality of discrete capture zones with receptors immobilized thereto, nor a particle having a size between 1 nm and 5 μ m with receptors immobilized thereto.

Because Stöcker does not disclose each and every limitation of the claimed invention, no *prima facie* case of anticipation has been established. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §102(b) be reconsidered and withdrawn.

Applicant further wishes to point out that, for certain dependent claims, the receptors for the target ligand(s) of interest are specifically defined as being antibodies, antibody fragments, nucleic acid molecules, and chelators. *See, e.g.*, claims 75, 77, 78, 80, 93, 95, 96, and 98. These claims have been alleged to be anticipated by Stöcker but the rejection fails to identify where the reference describes to immobilize antibodies, antibody fragments, nucleic acid molecules, or chelators. This failure to properly consider and address the language of each claim cannot support a *prima facie* case of anticipation of that claim. Applicant respectfully urges the Examiner to identify such support should the rejection of these dependent claims be maintained.

3. 35 U.S.C. § 103

Applicant respectfully traverses the rejection of claims 82 and 100 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Stöcker.

To establish a *prima facie* case of obviousness, three criteria must be met: there must be some motivation or suggestion, either in the cited references or in knowledge available to the ordinarily skilled artisan, to modify or combine the references; there must be a reasonable expectation of success in combining the references; and the references must teach or suggest all of the claim limitations. *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991) *See also*, MPEP §2143.

The Examiner asserts that the only deficiency between Stöcker and present claims 82 and 100 is the choice of materials from which the particles are made; that Stöcker is silent on the composition of “particles”; and that the use of latex, zirconia, alumina, titanium, *etc.*, would be obvious based on “their long track record of use with immunological materials.” Office Action, page 3. Applicant disagrees with these assertions.

As indicated above in the rebuttal to the rejection for anticipation, Stöcker fails to disclose all the elements of the claims. The noted deficiencies in Stöcker cannot be cured without additional teaching, which teaching is lacking from this obviousness rejection. Accordingly, the rejection for obviousness is without basis and should be withdrawn.

Applicant further notes that the rejection is also deficient in that it fails to comply with MPEP 2144.03(C) and provide evidence that the use of latex, zirconia, alumina, titanium, *etc.*, would be obvious based on “their long track record of use with immunological materials.” Compliance has been requested previously but continues to be lacking. Furthermore, Stöcker is not silent on the composition of the supports used to immobilize tissue samples. In fact, in all cases, the supports in Stöcker are made of thin glass. These glass “cover slip” supports are used so that a tissue sample may be emplaced on a large support, and the support then divided into smaller fragments. *See, e.g.*, Stöcker, claims. Nothing of record indicates that materials such as latex, zirconia, alumina, and titanium would be dividable in the manner that the glass supports disclosed in Stöcker are used, and thus might be obvious to use in place of Stöcker’s glass cover slips.

Because Stöcker does not teach or suggest the instantly claimed invention, Applicant respectfully submits that the Examiner has failed to establish a *prima facie* case of obviousness, and respectfully requests that the rejection be reconsidered and withdrawn.

Non-Art Based Remarks

4. 35 U.S.C. § 112, Second Paragraph

Applicant has amended claims 81 and 99 according to the Examiner’s suggestion. Applicant respectfully submits that the amendments to the claims render moot the rejection under 35 U.S.C. § 112, Second Paragraph.

Conclusion

Applicant respectfully submits that the pending claims are in condition for allowance. An early notice to that effect is earnestly solicited. Should any matters remain outstanding, the

Examiner is encouraged to contact the undersigned at the address and telephone number listed below so that they may be resolved without the need for additional action and response thereto.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

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